AT

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/462,911	02/15/2000	XAVIER ROUAU	54321.000013	5645

7590 09/07/2004

HUNTON & WILLIAMS
1900 K STREET NW
SUITE 1200
WASHINGTON, DC 20006-1109

EXAMINER	
MELLER, MICHAEL V	
ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 09/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/462,911	ROUAU ET AL.	
	Examiner	Art Unit	
	Michael V. Meller	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 June 2004 and 14 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-53* is/are pending in the application.

4a) Of the above claim(s) *24-27,30,31,38,39 and 44-52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28, 29, 32-37, 40-43, 53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

The restriction of record is maintained for the reasons of record. Applicant's election of group III is noted and the election was made FINAL in the previous office action. Applicant traversed the restriction saying that since lactose was not a galactose oligomer that there is a special technical feature but that is not the case as is evident from the rejections which follow. As stated in applicant's response dated 5/6/2003, applicant elected galactose oxidase and 1) galactose oligomer , 2) galactose oligomer and galactanase or 3) galactanase.

Thus, claims 24-27, 30,31, 38, 39 and 44-52 are withdrawn from further consideration as being drawn to non-elected subject matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28, 29, 32-37, 40-43, 53 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a galactanase, does not reasonably provide enablement for any and all enzymes which is capable of converting

a compound into a substrate for the galactose oxidase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The specification as filed, is enabled for a galactanase, but is not enabled for any and all enzymes which are capable of converting a compound into a substrate for the galactose oxidase.

The art of biotechnology is a highly unpredictable art and it would be an undue burden for one of ordinary skill in the art to test any and all enzymes to see if they possess the claimed function of the enzyme. The specification does teach that galactanase can perform this action but how can one of ordinary skill in the art test any and all enzymes to see if they could perform this action. The Patent office simply does not have the facilities to test such an enzyme.

Applicant has only shown in their specification one type of enzyme, namely glactanase. With only knowing this one enzyme it is clear that such broad claims are not enabled by the instant specification when one of ordinary skill in the art is only given one particular enzyme and expected to figure out which other enzymes are capable of converting a compound into a substrate for the galactose oxidase.

What compound ? What kind of compound ? Is it in with the galactose oxidase, where is it ? What conditions are required to do this ? What kind of enzyme is this, a protease, hydrolase, metalloproteinase ?

These questions are ones that one of ordinary skill in the art would not be able to answer and thus could not figure out what enzymes fall within this claim.

Applicant argues that they have shown other enzymes useful in the composition but these other enzymes are not necessarily the same "enzyme which is capable of hydrolyzing or otherwise degrading a compound into a substrate for the galactose oxidase". They have shown the enzymes on page 9, lines 31-34 but not the other enzymes that they are claiming. The other enzymes are merely being added and were not shown to be capable of hydrolyzing or otherwise degrading a compound into a substrate for the galactose oxidase.

.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28, 29, 32-37, 40-43, 53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase, "an enzyme which is capable of converting a compound into a substrate for the galactose oxidase" is confusing. What compound ? What kind of compound ? Is it in with the galactose oxidase, where is it ? What conditions are required to do this ? What kind of enzyme is this, a protease, hydrolase, metalloproteinase ?

Applicant argues that "compound" is understood in the art. A compound is just that, a specific structure and chemical formula. Applicants have provided neither.

It appears that applicant is also arguing that the "compound" is a galactan, galactose oligomer or a galactose dimer. It might be clearer if applicant defined the "compound" as a galactan, galactose oligomer or a galactose dimer.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 28, 29, 32-37, 40-43, 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beggs et al. (col. 5), Goers et al. '840 (col. 19), or Goers et al. '973 (col. 21) in view of WO 93/25239 (page 6), Jung et al. (abstract), Aoda et al. (col. 3), Wirth et al. (abstract), Morishita et al. (col. 11), or Baichwal et al. (col. 1).

Beggs et al. (col. 5), Goers et al. '840 (col. 19), or Goers et al. '973 (col. 21) each teach that galactose oxidase is known to be used in pharmaceutical compositions.

WO 93/25239 (page 6), Jung et al. (abstract), Aoda et al. (col. 3), Wirth et al. (abstract), Morishita et al. (col. 11), or Baichwal et al. (col. 1) teach that glactans are known in the art to be used in pharmaceutical compositions.

It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Sussman,* 1943 C.D. 518; *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Thus, the invention is obvious since the two components are both known in the art to be used for the same purpose, namely pharmaceutical purposes.

Applicant argues that the references do not teach a flour dough improving composition. These claims are to a product. The art does not have to teach the intended use of the claimed product. The references teach the claimed product for the reasons of record. Since the claims are drawn to the product and not the method of using the product, the claimed invention is properly rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-0967. The examiner can normally be reached on Monday thru Thursday: 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael V. Meller
Primary Examiner
Art Unit 1654

MVM